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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,099	08/08/2001	Yoshihiro Nishida	NISHIDA=3A	3370

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EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	10

DATE MAILED: 04/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,099	NISHIDA ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *1-13,16,17,20-36 and 39-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15,18,19,37 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/338,511* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8/8/01,3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's election with traverse of Group II invention, claims 12, 13, 16, 17, 35 and 36, in Paper No. 9, filed on 07 January 2003 is acknowledged. The traversal is on the ground(s) that examination of a product and two methods of use do not constitute a "serious burden". This is not found persuasive because consistent with current patent practice, a serious burden may be established by (A) separate classification thereof; (B) a separate status in the art when they are classifiable together; or (C) a different field of search. In the instant case, Groups I-III are patentably distinct inventions as shown by their separate classification, indicating each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. As stated in the MPEP 803, "a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 802.02.". Further, a search is directed not only to art which would be anticipatory, but also to art that would render the invention obvious. Thus, the groups require divergent searches, and to search all groups of inventions would constitute serious burden.

The requirement is still deemed proper and is therefore made FINAL.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

There are two sets of claims 10 and 11. Misnumbered claims 10 (the second one) to 44 have been renumbered claims 12 to 46.

Currently, claims 1-46 are pending, and claims 14, 15, 18, 19, 37 and 38 are under consideration. Accordingly, claims 1-13, 16, 17, 20-36, and 39-46, as non-elected inventions, are withdrawn from consideration.

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Claims 14, 15, 18, 19, 37 and 38 are objected to as being dependent upon a non-elected claim. The applicant is required to rewritten the claim in independent form including all of the limitations of the base claim and any intervening claims.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 19 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite because it is unclear what "autoimmunity (...) treatment" refers to, and why one would seek to enhance autoimmunity. Claims 19 and 38 are similarly indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 18 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a method to treat for alleviating a disease with said composition, does not reasonably provide enablement for claims to a method to treat for *preventing or remedying* a disease with said composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of

direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 14, 18 and 37 are directed to a method to treat for preventing, alleviating, or remedying a disease such as asthma, or rheumatoid arthritis, etc. with said composition. The claim limitation of preventing or remedying a disease reads on to keep the disease from happening or to cure the disease. In searching the prior art, the results of record have not established that a disease such as asthma, or rheumatoid arthritis can be prevented or cured by an anti-IL-18 antibody, or a composition capable of neutralizing or antagonizing IL-18 activity, or any other composition. Further, the specification provides no instruction or guidance, nor working examples of in the respect to the preventing or curing effect of anti-IL-18 antibodies on said diseases. Furthermore, prevention would necessarily mean that an individual would be given said composition, and such administration would ensure that the patient did not develop said diseases. As currently there is no decisive means to predict who would be developing the conditions, and such preventative or curing effect has not been shown, the asserted use of *preventing or remedying* the diseases is not enabled.

Due to the large quantity of experimentation necessary to determine the preventing or remedying effect of the anti-IL-18 antibody, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art, which has not established that said diseases or conditions can be prevented or cured by antagonizing IL-18 activity, and the breadth of the claims which embraces preventative or curing effect of the composition, undue experimentation would be required of the skilled artisan to use the claimed invention in its full scope.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14, 15, 18, 19, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taniguchi et al. (J Immunol. Methods, 1997, 206: 107-113, provided by applicants), in view of Kohno et al. (Clin. Immunol. Immunopath., January 1998, 86(1): 11-15).

Taniguchi discloses an anit-human IL-18 monoclonal antibody, #125-2H, which is identical to that of the instant application, as both the prior art and the present monoclonal antibodies are from the same hybridoma. Additionally, the reference teaches that the mAb has neutralizing activity, and is capable of inhibiting IL-18 bioactivity (page 110, the right column, and Table 1). The prior art monoclonal antibody meets the limitation of the independent claim 1 of the instant application as it is "an artificially produced peptide" neutralizing a biological activity of IL-18. Further, the prior art mAb also meet the limitations of claims 12, 16 and 35 from which claims 14, 15, 18, 19, 37 and 38 are indirectly dependent, as the cited properties would be inherent for the prior art mAb since it meets the limitation of claim 1. Although the reference does not explicitly teach "a pharmaceutically acceptable carrier" with the mAb as that in the present claims 13, 17 and 36 from which claims 14, 15, 18, 19, 37 and 38 are dependent, however, Taniguchi's mAb is used in combination with buffer or media, which are considered "a pharmaceutically acceptable carrier". As such, the prior art mAb anticipates the composition or the agent used in the methods of claims 14, 15, 18, 19, 37 and 38.

The primary reference does not teach a method to treat a living body for preventing, alleviating, or remedying said diseases using the antibody.

Kohno teaches that administration of anti-IL-18 antibodies completely reversed the endotoxin-induced liver injury, indicating pathological role of IL-18 (page 14, the left column). Further, the reference summaries the findings of the prior art as to IL-18 and diseases, indicating

pathological role of IL-18 in other diseases such as autoimmune insulitis and diabetes, and rheumatoid arthritis (RA), and suggesting that IL-18 may be involved in chronic inflammation and joint detraction in RA patients (page 14, the last paragraph of the left column, and the first paragraph of the right column).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the antibody taught by Taniguchi for the treatment of diseases such as RA and those associated with autoimmunity because Kohno teaches a pathological role of IL-18 in these diseases, and Taniguchi's antibody is capable of neutralizing IL-18. The person of ordinary skill in the art would have been motivated to do so for the therapeutic purpose, and reasonably would have expected success because Kohno has demonstrated successful application of anti-IL-18 antibodies in treating pathological conditions.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
4/8/03